



BAY CENTER MARICULTURE CO.

Post Office Box 356 • Bay Center, Washington • 98527

Mr. William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Admist.
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

6380 '99 April 12, 1999
APR 15 1999

RE: Request for Information on performance Standard for Vibrio vulnificus.
Docket #98P-0504: Vol 64; No. 13; pp. 3300-3301.

Dear Mr. Hubbard,

This letter is in response to the request for information by your agency on this very important matter of possibly stopping live shellfish sales from areas with detectable levels of *Vibrio vulnificus* (and probably *V. parahaemolyticus*). The action by your agency comes in response to a consumer group petition and it would modify if not eliminate major portions of the west coast shellfish industry. Our association, the PCOGA, has replied to the eight questions asked by the FDA and those views are also those of this company. The comments which follow will not address these points directly but will attempt to point out how our company would be impacted or eliminated by the proposed actions.

Our oyster growing and processing company on Willapa Bay on a yearly average employs around twenty full time workers, and has built a strong market for our specially cultured live in-shell oysters. We shipped over 100,000 dozen live oysters in the shell during 1998 which accounted for a major percentage of our sales. We daily clean and chill each shipment before they are transported by refrigerated trucks to their final destination. We have never had a complaint on our product. Our customers buy our oysters because they are raw and alive and would not purchase a treated more expensive dead oyster.

Through our regional association (PCOGA) we have learned that *Vibrio parahaemolyticus* would also likely be considered for this post harvest treatment which would not be available to us because of cost constraints. This is particularly troubling when there has not been a standard set for what would be an acceptable health level for these naturally occurring bacteria. I suspect low levels of both *V. parahaemolyticus* and *V. vulnificus* could be present at times in Willapa Bay just as with *E. coli* and it would seem that the first order of business for FDA would be to establish a scientifically based action level (other than zero) for these natural bacteria.

The State of Washington's Department of Health has a very good monitoring plan for marine toxins and bacteria levels. Several weekly samples from localities throughout the state are sent in during the year and the information is readily available at any time by the growers and processors. The Department of Health can contact all shellfish growers and harvesters literally within minutes if a health concern should arise. It has to be realized in our business the biggest concern is that one of our customers will get sick from our product. Although we have never had this happen, our company is always ready to cease harvesting if any potential problem should be discovered.

Our company, which I founded in 1971, has become an important economic factor in this economically poor area in SW Washington. Shellfish farming is one of the major industries in this

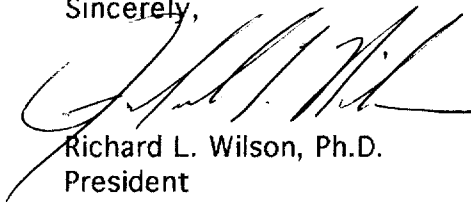
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area. If the FDA should set a standard where we could not sell live oysters and clams from our farm then it would dramatically alter the way we could do business. At the very least we would be reduced to around or less than half the current levels in all aspects such as employees, sales, etc. Willapa Bay is very clean and the oyster industry spends a great deal of time making sure it stays that way. There would be little, or certainly less, reason to have a clean bay if the shellfish industry is greatly reduced or ceased to exist. The elimination of the sale of live oysters and clams from Willapa Bay would probably be the necessary action to slow down or stop over 100 years of oyster farming on the tidelands of this bay.

I would like to urge the FDA to work within the ISSC forum to outline the necessary research and then formulate a plan to determine the exact health risks with regard to *Vibrio* concentrations. After those steps are taken the information can be used as a basis to develop appropriate public health guidelines for the shellfish industry to follow.

Sincerely,

A handwritten signature in black ink, appearing to read 'Richard L. Wilson', is written over the typed name and title.

Richard L. Wilson, Ph.D.
President

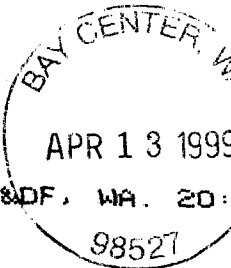
cc. Representative Brian Baird
Senator Slade Gorton
Senator Patty Murray



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